

PATENT COOPERATION TREATY

GlaxoSmithKline
Corporate IP

18 MAY 2004

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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17 MAY 2004

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

ATTY: <i>[Signature]</i>	ADMIN: <i>[Signature]</i>
IPM: <i>[Signature]</i>	ON: <i>[Signature]</i>
ATTY CHECKED: <i>[Signature]</i>	DATE OF MAILING: <i>[Signature]</i>

14.05.2004

Applicant's or agent's file reference
JNR/PG4886A

IMPORTANT NOTIFICATION

International application No.
PCT/EP 03/08150

International filing date (day/month/year)
23.07.2003

Priority date (day/month/year)
25.07.2002

Applicant
GLAXO GROUP LIMITED et Al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
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Form PCT/PEA/416 (January 2004)

Express Mail Label No.
EV332145279US

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference JNR/PG4886A	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/08150	International filing date (day/month/year) 23.07.2003	Priority date (day/month/year) 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 27.01.2004	Date of completion of this report 14.05.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/08150**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-59 as originally filed

Claims, Numbers

1-36 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/08150**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 36

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 36

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-30
	No: Claims	1, 31-35
Inventive step (IS)	Yes: Claims	-
	No: Claims	1-35
Industrial applicability (IA)	Yes: Claims	1-35
	No: Claims	-

2. Citations and explanations

see separate sheet

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EXAMINATION REPORT - SEPARATE SHEET**

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Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 36 was not searched in view of Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT and therefore no substantive examination can be performed.

Moreover, claim 36 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated on the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject-matter of claim 1 is not new (Article 33(2) PCT).

The document WO-A-0064519 discloses (see page 3, line 21 to page 8, line 19):

a medicament dispenser device for use in the delivery of a combination medicament product, the device comprising
a first medicament container (1) for containing a first medicament component;
a first release means (6, 7b) for releasing the contents of said first medicament container (1);
at least one further medicament container (2) for containing at least one further medicament component; and
at least one further release means (6, 7a) for releasing the contents of each said at least one further medicament container (2);
wherein the first medicament component is kept separate from the at least one further medicament component until the point of release thereof for delivery in combination (page 4, lines 29 to 37), and wherein the dispenser device additionally comprises
at least one actuation indicator (page 8, lines 15 to 19) associated with the first medicament container and/or the at least one further medicament container

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

This objection holds also in view of documents WO-A-0204055 (page 1, line 16 to page

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5, line 31), US-A-5524613 (column 6, line 6 to column 11, line 15), WO-A-0139823 (page 5, line 22 to page 9, line 14).

Dependent claims 2-35 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty and/or inventive step, the reasons being as follows:

Claims 2 to 27 all relate to the implementation of the actuation indicator in a specific known type of inhaler device (see also claim 28). Each of these specific inhaler devices is normally equipped with an actuation indicator, as the need for information on dispensed and/or available doses arises in each of these inhalers. The embodiment with one separate actuator indicator for each medicament container would be obvious to the skilled person. An embodiment using only one actuation indicator for more than one medicament containers is likewise obvious. The skilled person would consider the resulting technical changes involved in these embodiments (simultaneous actuation) a normal design procedure. Therefore, claims 2 to 27 do not involve an inventive step (Article 33(3) PCT). Claims 28 to 30 are well-known features of inhaler devices (see WO-A-0064519, page 4, line 29 to page 5, line 7). These claims do not involve an inventive step (Article 33(3) PCT).

Claims 31 to 35 relate to the medicaments used with the inhaler device. These combinations of medicaments are disclosed in the prior art documents (see e.g. WO-A-0064519, page 2, lines 1 to 3 and page 4, lines 1 to 11). Claims 31 to 35 are therefore not new (Article 33(2) PCT).

The medicament dispenser device disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met.

Claims 2 to 35 depend from claim 1 and refer to further embodiments of the medicament dispenser device described in claim 1 and thus meet the requirements of Article 33(4) PCT for the same reasons explained above.

The following document is cited under Rule 70.10 PCT, as it constitutes prior art for the

**INTERNATIONAL PRELIMINARY
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International application No. PCT/EP03/08150

purposes of Article 33(2) PCT for claims 1 - 9 and 12 - 35.

Certain published documents

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-03061743	31-07-2003	22-01-2003	25-01-2003